

MEDICAL POLICY



SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) CARDIAC APPLICATIONS POLICY NUMBER: 6.01.41 CATEGORY: Technology Assessment	EFFECTIVE DATE: 04/19/12 REVISED DATE: 04/18/13, 02/20/14, 03/19/15, 02/18/16, 02/16/17, 02/15/18 PAGE: 1 OF: 5
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

Based upon our criteria and assessment of peer reviewed literature, FDG positron emission tomography (PET) using a full ring dedicated PET scanner is considered **medically appropriate** for the following cardiac indications using radiotracer FDG rubidium 82 (Rb-82) or nitrogen ammonia 13 (ammonia N-13):

- I. To assess myocardial perfusion and thus diagnose coronary artery disease in patients with indeterminate SPECT imaging.
- II. May be used in place of SPECT imaging for patients with conditions that may cause significant attenuation problems with SPECT; such as morbid obesity (Body Mass Index greater than 35 kg/m²), chest wall deformity, large breasts, breast implants.
- III. Routine use in post heart transplant assessment of transplant CAD; may image annually.
- IV. To assess myocardial viability in patients with severe left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure.
- V. Clinical suspicion of cardiac sarcoid in patients unable to undergo MRI scanning (e.g., patients with pacemakers, automatic implanted cardioverter-defibrillators (AICDs), or other metal implants).

Refer to Corporate Medical Policy #6.01.07 regarding Positron Emission Tomography-NonOncologic Applications.

Refer to Corporate Medical Policy #6.01.29 regarding Positron Emission Tomography-Oncologic Applications.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

POLICY GUIDELINES:

- I. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.
- II. 3D rendering, (CPT®76376/CPT®76377), should not be billed in conjunction with PET.

DESCRIPTION:

Positron emission tomography (PET) is an imaging technology that can reveal metabolic information in various tissue sites. The metabolic information is what distinguishes it from other imaging modalities such as magnetic resonance imaging (MRI) and computed tomography (CT) that provide primarily anatomic information. PET scanning can be used to identify coronary artery disease by identifying perfusion defects, to assess myocardial viability in patients with left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure and may potentially be used to measure myocardial blood flow and blood flow reserve. Cardiac PET is also being studied for evaluation of coronary artery inflammation. PET scans measure concentrations of radioactive chemicals that are partially metabolized in the body and are based on the use of positron emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. Dedicated PET scanners consist of multiple detectors arranged in a full or partial ring around the patient.

A variety of radiotracers are used for PET scanning including fluorine-18, rubidium-82, ammonia N-13, carbon-11, oxygen-15 and nitrogen-13. Fluorine-18 is often coupled with fluoreodeoxyglucose (FDG) as a means of detecting glucose metabolism, which in turn reflects the metabolic activity, and thus viability, of the target tissue. Because of their

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) CARDIAC APPLICATIONS POLICY NUMBER: 6.01.41 CATEGORY: Technology Assessment	EFFECTIVE DATE: 04/19/12 REVISED DATE: 04/18/13, 02/20/14, 03/19/15, 02/18/16, 02/16/17, 02/15/18 PAGE: 2 OF: 5
--	--

short half-life, tracers must be made locally. With exception of fluorine and rubidium all the tracers must be manufactured with an on-site cyclotron.

PET has emerged as an important alternative perfusion imaging modality due to recent shortages of molybdenum-99/technetium-99m (99mTc). It is a well-established modality for evaluation of myocardial blood flow (MBF) as well as, for assessment of myocardial metabolism and viability in patients with ischemic left ventricular (LV) dysfunction. Potential future applications of PET for plaque and molecular imaging and for use in inflammatory conditions.

RATIONALE:

The U.S. Food and Drug Administration (FDA) has approved the scanner and imaging hardware for PET as being substantially equivalent to x-ray computed tomography (CT). The FDA requires PET radiotracers to be approved through a new drug approval (NDA) process. Because PET radiotracers have an extremely short half-life, they must be produced in the clinical setting. The FDA also intends to regulate drug manufacturing processes in PET facilities. In 1991 the FDA approved the use of Rubidium 82 (Rb 82) as a myocardial perfusion tracer and in 1999 approved the use of ammonia N-13 as a myocardial perfusion tracer.

Clinical evidence supports that the use of Rubidium 82 (Rb-82) PET and ammonia N-13 PET scans in clinical practice has the potential to improve net health outcomes through changes in patient management. Studies demonstrate that both tracers have high reliability and validity in the evaluation of myocardial perfusion.

In 2009, the American College of Cardiology (ACC) and the American Heart Association (AHA) published updated guidelines for cardiac radionuclide imaging. Sixty-seven clinical scenarios were developed by a writing group and scored by a separate technical panel on a scale of 1 to 9 to designate appropriate use, inappropriate use, or uncertain use. In general, use of cardiac RNI for diagnosis and risk assessment in intermediate- and high-risk patients with coronary artery disease (CAD) was viewed favorably, while testing in low-risk patients, routine repeat testing, and general screening in certain clinical scenarios were viewed less favorably. Additionally, use for perioperative testing was found to be inappropriate except for high selected groups of patients. It is anticipated that these results will have a significant impact on physician decision making, test performance, and reimbursement policy, and will help guide future research.

2011 Appropriateness Criteria from the American College of Radiology (ACR) considers both SPECT and PET to be appropriate for the evaluation of patients with a high probability of coronary artery disease. ACR states that PET perfusion imaging has advantages over SPECT, including higher spatial and temporal resolution. Routine performance of both PET and SPECT are not necessary.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

<u>CPT:</u>	78459	Myocardial imaging, (PET), metabolic evaluation
	78491	Myocardial imaging, positron emission tomography, (PET), perfusion; single study at rest or stress
	78492	multiple studies at rest and/or stress
	0482T	Absolute quantitation of myocardial blood flow, positron emission tomography (PET), rest and stress (List separately in addition to code for primary procedure) (<i>effective 1/1/2018</i>)

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) CARDIAC APPLICATIONS POLICY NUMBER: 6.01.41 CATEGORY: Technology Assessment	EFFECTIVE DATE: 04/19/12 REVISED DATE: 04/18/13, 02/20/14, 03/19/15, 02/18/16, 02/16/17, 02/15/18 PAGE: 3 OF: 5
--	--

<u>HCPCS:</u>	A9526	Nitrogen N-13 ammonia, diagnostic, per study dose, up to 40 millicuries
	A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
	A9555	Rubidium Rb-82, diagnostic, per study dose, up to 60 millicuries
	S8085 (E/I)	Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan)
<u>ICD10:</u>	I25.10-I25.119	Atherosclerotic heart disease of native coronary artery with or without angina pectoris (code range)
	I25.700-I25.739	Atherosclerosis of autologous vein or artery coronary artery bypass graft(s) with angina pectoris (code range)
	I25.790-I25.799	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris (code range)
	I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
	I51.9	Heart disease, unspecified
	I52	Other heart disorders in diseases classified elsewhere

REFERENCES:

Blankstein R, et al. Cardiac positron emission tomography enhances prognostic assessment of patients with suspected cardiac sarcoidosis. J Am Coll Cardiol 2014 Feb 4;63(4):329-36.

BlueCross BlueShield Association. Cardiac applications of PET scanning. Medical Policy Reference Manual. Policy #6.01.20. 2017 Sep 14.

BlueCross BlueShield Association. FDG using camera-based imaging (FDG-SPECT). Medical Policy Reference Manual Policy #6.01.27. 2009 Dec 03.

BlueCross BlueShield Association. Miscellaneous applications of positron emission tomography (PET). Medical Policy Reference Manual Policy #6.01.06. 2017 Sep 14.

Bucerius J, et al. Position paper of the Cardiovascular Committee of the European Association of Nuclear Medicine (EANM) on PET imaging of atherosclerosis. Eur J Nucl Med Mol Imaging 2016 Apr;43(4):780-92.

*Dhar R, et al. Rubidium-82 positron emission tomography imaging: an overview for the general cardiologist. Cardiol Rev 2011 Sep-Oct;19(6):255-63.

Dorbala S, et al. Prognostic value of stress myocardial perfusion positron emission tomography: results from a multicenter observational registry. J Am Coll Cardiol 2013 Jan 15;61(2):176-84.

Earls JP, et al. ACR Appropriateness Criteria asymptomatic patient at risk for coronary artery disease. J Am Coll Radiol 2014;11(1):12-9.

*Earls JP, et al. ACR Appropriateness Criteria(R) chronic chest pain--high probability of coronary artery disease. J Am Coll Radiol 2011; 8(10):679-86.

*Fleisher LA, et al. ACC/AHA 2007 guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery: a report of the American College of Cardiology/American Heart Association task force on practice guidelines. Circulation 2007;116:e418-500.

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) CARDIAC APPLICATIONS POLICY NUMBER: 6.01.41 CATEGORY: Technology Assessment	EFFECTIVE DATE: 04/19/12 REVISED DATE: 04/18/13, 02/20/14, 03/19/15, 02/18/16, 02/16/17, 02/15/18 PAGE: 4 OF: 5
--	--

*Greenland P, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines developed in collaboration with the American Society of Echocardiography, American Society of Nuclear Cardiology, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. J Am Coll Cardiol 2010;56:e50-103.

*Hendel KA, et al. ACCF/ASNC/ACF/AHA/ASE/SCCT/SCMR/SNM 2009 appropriate use criteria for cardiac radionuclide imaging. J Am Coll Cardiol 2009;59:2201-29.

*Hove JD, et al. Simultaneous cardiac output and regional myocardial perfusion determination with PET and nitrogen 13 ammonia. J Nucl Cardiol 2003 Jan-Feb;10(1):28-33.

*Ibrahim T, et al. Assessment of coronary flow reserve: comparison between contrast-enhanced magnetic resonance imaging and positron emission tomography. J Am Coll Cardiol 2002 Mar 6;39(5):864-70.

Ito K, et al. Visual findings of 18F-fluorodeoxyglucose positron emission tomography/computed tomography in patients with cardiac sarcoidosis. Intern Med 2014;53(18):2041-9.

*Jaarsma C, et al. Diagnostic performance of noninvasive myocardial perfusion imaging using single-photon emission computed tomography, cardiac magnetic resonance, and positron emission tomography imaging for the detection of obstructive coronary artery disease: a meta-analysis. J Am Coll Cardiol 2012;59(19):1719-28.

*Kanayama S, et al. Assessment of global and regional left ventricular function by electrocardiographic gated N-13 ammonia positron emission tomography in patients with coronary artery disease. Circ J 2005 Feb;69(2):177-82.

McArdle B, et al. Cardiac PET: metabolic and functional imaging of the myocardium. Semin Nucl Med 2013 Nov;43(6):434-48.

McDiarmid AK, et al. Emerging imaging techniques after cardiac transplantation. J Heart Lung Transplant. 2016 Dec;35(12):1399-1411.

Miyagawa M, et al. Positron emission tomography-computed tomography for imaging of inflammatory cardiovascular diseases. Circ J 2014;78(6):1302-10.

*Nakazato R, et al. Myocardial perfusion imaging with PET. Imaging Med 2013 Feb1;5(1):35-46.

*Parker MW, et al. Diagnostic accuracy of cardiac positron emission tomography versus single photon emission computed tomography for coronary artery disease: a bivariate meta-analysis. Circ Cardiovasc Imaging 2012 Nov;5(6):700-7.

*Santana CA, et al. Incremental prognostic value of left ventricular function by myocardial ECG-gated FDG PET imaging in patients with ischemic cardiomyopathy. J Nucl Cardiol 2004 Sep-Oct;11(5):542-50.

Sechtem U, et al. The year in cardiology 2013: imaging in ischaemic heart disease. Eur Heart J 2014 Feb;35(6):344-8.

*Singh TP, et al. Positron emission tomography myocardial perfusion imaging in children with suspected coronary abnormalities. Pediatr Cardiol 2003 Mar-Apr;24(2):138-44.

*Slart RH, et al. Prediction of functional recovery after revascularization in patients with chronic ischaemic left ventricular dysfunction: head-to-head comparison between (99m)Tc-sestamibi/(18)F-FDG DISA SPECT and (13)N-ammonia/(18)F-FDG PET. Eur J Nucl Med Mol Imag 2006 Jun;33(6):716-23.

*Walter MA, et al. The value of [18F]FDG-PET in the diagnosis of large-vessel vasculitis and the assessment of activity and extent of disease. Eur J Nucl Med Mol Imag 2005 Jun;32(6):674-81.

* key article

KEY WORDS:

FDG PET, FDG SPECT, Gamma Camera, Ammonia N-13, Rubidium 82.

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) CARDIAC APPLICATIONS	EFFECTIVE DATE: 04/19/12
POLICY NUMBER: 6.01.41	REVISED DATE: 04/18/13, 02/20/14, 03/19/15, 02/18/16, 02/16/17, 02/15/18
CATEGORY: Technology Assessment	PAGE: 5 OF: 5

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for PET scans. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=211&ncdver=4&bc=AgAAgAAAAAAA&>.